CARDIAC RHYTHM MANAGEMENT SYSTEM
FOR HYPOTENSION

Technical Field

5

The present system relates generally to cardiac rhythm management systems and particularly, but not by way of limitation, to a such a system for hypotension.

Background

10   When functioning properly, the human heart maintains its own intrinsic rhythm, and is capable of pumping adequate blood throughout the body's circulatory system. However, some people have irregular cardiac rhythms, referred to as cardiac arrhythmias. Such arrhythmias result in diminished blood circulation. One mode of treating cardiac arrhythmias uses drug therapy. Drugs are often effective at

15 restoring normal heart rhythms. However, drug therapy is not always effective for treating arrhythmias of certain patients. For such patients, an alternative mode of treatment is needed. One such alternative mode of treatment includes the use of a cardiac rhythm management system. Such systems are often implanted in the patient and deliver therapy to the heart.

20   Cardiac rhythm management systems include, among other things, pacemakers, also referred to as pacers. Pacers deliver timed sequences of low energy electrical stimuli, called pace pulses, to the heart, such as via an intravascular leadwire or catheter (referred to as a "lead") having one or more electrodes disposed in or about the heart. Heart contractions are initiated in response to such pace pulses

25 (this is referred to as "capturing" the heart). By properly timing the delivery of pace pulses, the heart can be induced to contract in proper rhythm, greatly improving its efficiency as a pump. Pacers are often used to treat patients with bradyarrhythmias, that is, hearts that beat too slowly, or irregularly. Such pacers coordinate atrial and ventricular contractions to improve pumping efficiency. Cardiac rhythm

30 management systems also include coordination devices for coordinating the

1

contractions of both the right and left sides of the heart for improved pumping efficiency.

Cardiac rhythm management systems also include defibrillators that are capable of delivering higher energy electrical stimuli to the heart. Such defibrillators also include cardioverters, which synchronize the delivery of such

5   stimuli to portions of sensed intrinsic heart activity signals. Defibrillators are often used to treat patients with tachyarrhythmias, that is, hearts that beat too quickly. Such too-fast heart rhythms also cause diminished blood circulation because the heart isn't allowed sufficient time to fill with blood before contracting to expel the blood. Such pumping by the heart is inefficient. A defibrillator is capable of

10   delivering an high energy electrical stimulus that is sometimes referred to as a defibrillation countershock, also referred to simply as a "shock." The countershock interrupts the tachyarrhythmia, allowing the heart to reestablish a normal rhythm for the efficient pumping of blood. In addition to pacers, cardiac rhythm management systems also include, among other things, pacer/defibrillators that combine the

15   functions of pacers and defibrillators, drug delivery devices, and any other implantable or external systems or devices for diagnosing or treating cardiac arrhythmias.

One problem faced by some patients is hypotension, that is, low blood pressure. Hypotension can result in dizziness, sometimes referred to as presyncope.

20   Hypotension can even lead to unconsciousness, sometimes referred to as syncope. One cause of hypotension is an excess shifting of blood in the circulatory system toward the extremities (arms and legs) and away from vital organs in the patient's head and thorax. This can occur, for example, when the patient changes posture from lying horizontal or sitting with legs elevated to a position in which the patient

25   is sitting or standing erect. Hypotension resulting from such changes in posture is referred to herein as orthostatic hypotension. However, hypotension may also have causes other than changes in posture. For example, maintaining the same posture for an extended period of time (e.g., sitting erect during an intercontinental airplane

2

flight) may also cause hypotension. Moreover, certain cardiovascular disorders may result in hypotension independent of postural changes, or may exacerbate orthostatic hypotension.

For example, disautonomic syncope is a problem with the autonomic nervous system. In normal patients, the autonomic nervous system constricts the

5   blood vessels in the extremities in response to a change to a more upright posture. This venoconstriction of the blood vessels in the extremities reduces the amount of blood that would otherwise shift to the extremities when the patient changes to a more upright posture. In some patients, however, this response by the autonomic nervous system is absent, or is even reversed by a venodilation of blood vessels in

10   the extremities. Such patients are likely to experience hypotension. Moreover, this deficient response by the autonomic nervous system may occur even without changes in posture, leading to hypotension that is not necessarily orthostatic in nature.

Another example of a cardiovascular cause of hypotension is vasovagal

15   syncope. In normal patients, a change to a more upright posture results in an increased heart rate. For example, for a patient that is at rest, the heart rate may temporarily increase from 60 beats per minute (bpm) to 80 bpm when the patient stands up after laying horizontally. In some patients, however, this autonomic response is absent—resulting in a drop in heart rate. This may also lead to

20   hypotension as blood shifts away from the head and thorax into the extremities. Regardless of the cause of hypotension, the resulting symptoms of dizziness or loss of consciousness may be extremely dangerous. This is particularly so for elderly patients who are at increased risk of injury from a fall resulting from the dizziness or loss of consciousness. Hypotension is also an obvious danger for persons operating

25   motor vehicles or other machinery. For these and other reasons, there is a need to treat hypotension to avoid these symptoms and associated risks.

Summary of the Invention

This document discusses, among other things, a cardiac rhythm management system using thoracic impedance measurements to detect and treat hypotension. In one embodiment, the system receives a thoracic impedance signal. An averager or other lowpass filter obtains a baseline portion of the thoracic impedance signal that

5   is associated with a fluid shift away from the thorax. A rate of pacing therapy is increased in response to the detected fluid shift away from the thorax to treat the hypotension. Several other therapies are also discussed. Other aspects of the invention will be apparent on reading the following detailed description of the invention and viewing the drawings that form a part thereof.

10

Brief Description of the Drawings

In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially

15   similar components.

Figure 1 is a schematic/block diagram illustrating generally one embodiment of portions of a cardiac rhythm management system.

Figure 2 is a block diagram illustrating generally one embodiment of portions of a signal processor associated with detecting hypotension based on

20   thoracic impedance.

Figure 3 is a schematic/block diagram illustrating generally, one embodiment of portions of a hypotension detection module.

Figure 4 is a schematic/block diagram illustrating generally, one embodiment of portions of a hypotension detection module.

25   Figure 5 is a block diagram illustrating generally one embodiment of portions of a blending module providing an indicated pacing rate based on activity, breathing, and/or a thoracic impedance-based measurement of hypotension.

Figure 6 is a schematic illustration of an alternate electrode arrangement

4

including one or more defibrillation electrodes.

Figure **7** is a schematic illustration of an alternate electrode arrangement including one or more atrial electrodes.

Figure **8** is a schematic illustration of an alternate electrode arrangement including one or more left heart electrodes such as, for example, left ventricular

5   electrodes.

Figure **9** is a schematic illustration of an alternate electrode arrangement for measuring a component of thoracic impedance between atrial electrodes and ventricular electrodes.

Figure **10** is a schematic illustration of an alternate electrode arrangement for

10   measuring a component of thoracic impedance between right heart (e.g., right ventricular) and left heart (e.g., left ventricular) electrodes.

Detailed Description

In the following detailed description, reference is made to the accompanying

15   drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the embodiments may be combined, or that other embodiments may be utilized and that structural, logical and electrical changes

20   may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents. In the drawings, like numerals describe substantially similar components throughout the several views. Like numerals having different letter

25   suffixes represent different instances of substantially similar components. The term "and/or" refers to a nonexclusive "or" (i.e., "A and/or B" includes both "A and B" as well as "A or B").

The present methods and apparatus will be discussed in applications

5

involving implantable medical devices including, but not limited to, implantable cardiac rhythm management systems such as pacemakers, cardioverter/defibrillators, pacer/defibrillators, and biventricular or other multi-site coordination devices. However, it is understood that the present methods and apparatus may be employed in unimplanted devices, including, but not limited to, external pacemakers,

5   cardioverter/defibrillators, pacer/defibrillators, biventricular or other multi-site coordination devices, monitors, programmers and recorders.

This document discusses a cardiac rhythm management system that detects hypotension by measuring an impedance across a portion of a patient's thorax, referred to as "transthoracic impedance" or simply abbreviated as "thoracic

10   impedance." In this document, the term thorax is understood to include the portion of the subject's body other than the head, arms, and legs. The system provides appropriate responsive therapy, such as by adjusting the rate of delivery of pacing stimuli to the heart to help avoid symptoms associated with hypotension, such as dizziness or fainting.

15   <u>Electrode Configuration and Top-Level Block Diagram</u>

Figure 1 is a schematic/block diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of a cardiac rhythm management system **100** according to the present invention. In this embodiment, system **100** includes, among other things, cardiac rhythm management device **105**

20   and leadwire ("lead") **110** for communicating signals between device **105** and a portion of a living organism, such as heart **115**. Embodiments of device **105** include, among other things, bradycardia and antitachycardia pacemakers, cardioverters, defibrillators, combination pacemaker/defibrillators, drug delivery devices, and any other implantable or external cardiac rhythm management

25   apparatus capable of providing therapy to heart **115**. System **100** may also include additional components such as, for example, a remote programmer **190** capable of communicating with device **105** via a transmitter or receiver, such as telemetry transceiver **185**.

In one embodiment, portions of system **100** (e.g., device **105**) are implantable in the living organism, such as in a pectoral or abdominal region of a human patient, or elsewhere. In another embodiment, portions of system **100** (e.g., device **105**) are alternatively disposed externally to the human patient. In the illustrated embodiment, portions of lead **110** are disposed in the right ventricle,

5   however, any other positioning of lead **110** is included within the present invention. For example, lead **110** may alternatively be positioned in a location that is associated with the right atrium and/or superior vena cava, the coronary sinus or great cardiac vein, the left atrium or ventricle, epicardially, or elsewhere. In one embodiment, lead **110** is a commercially available bipolar pacing lead. System **100** can also

10   include other leads in addition to or instead of lead **110**, appropriately disposed, such as in or around heart **115**, or elsewhere. In one external embodiment, lead **110** is disposed external to the patient and includes external skin electrodes that are associated with the heart and/or thorax.

In one embodiment, system **100** includes at least four electrodes, such as

15   discussed in Hauck et al. U.S. Patent 5,284,136 entitled "DUAL INDIFFERENT ELECTRODE PACEMAKER," assigned to Cardiac Pacemakers, Inc., the disclosure of which is incorporated herein by reference in its entirety. It is understood, however, that the present invention also includes using a different number of electrodes (e.g., 2 or 3 electrodes, or more than 4 electrodes). In one

20   example, a first conductor of multiconductor lead **110** electrically couples a first electrode, such as tip electrode **120** (e.g., disposed at the apex of the right ventricle of heart **115**), to device **105**. A second conductor of multiconductor lead **110** independently electrically couples a second electrode, such as ring electrode **125**, to device **105**. In one embodiment, device **105** includes a hermetically sealed housing

25   **130**, formed from a conductive metal, such as titanium. Housing **130** (also referred to as a "case" or "can") is substantially covered over its entire surface by a suitable insulator, such as silicone rubber, except for at a window that forms a third electrode, referred to as a "case" or "can" or "housing" electrode **135**. In one

7

embodiment, a header **140** is mounted on housing **130** for receiving lead **110**.
Header **140** is formed of an insulative material, such as molded plastic. In the
illustrated embodiment, header **140** also includes at least one receptacle, such as for
receiving lead **110** and electrically coupling conductors of lead **110** to device **105**.
Header **140** also includes a fourth electrode, referred to as indifferent electrode **145**.

5   Figure 1 also illustrates generally portions of device **105**, together with
schematic illustrations of connections to the various electrodes. Device **105**
includes an electrical energy source serving as a test signal generator, such as exciter
150. Exciter **150** delivers an electrical test energy, such as a strobed sequence of
current pulses or other test energy, to heart **115** (e.g., between ring electrode **125** and

10   tip electrode **120**, or using any other electrode configuration suitable for delivering
the current pulses). In response to the excitation signal provided by exciter **150**, a
response signal is sensed by signal processor **155** (e.g., between tip electrode **120**
and indifferent electrode **145**, or using any other suitable electrode configuration).
The electrical excitation signal is also referred to herein as a test signal or test

15   stimulus because it serves as an active energy source from which a heart impedance
is detected; however, it is understood that this signal need not, and typically does
not, have the magnitude of energy required to excite or stimulate cardiac or other
muscular tissue to contract. Instead, the excitation signal need only provide enough
response for the signal processor to obtain useful information about heart

20   impedance. Moreover, while the illustrated embodiment uses a current excitation
stimulus to obtain a voltage response signal from which heart impedance can be
determined, it is understood that a voltage excitation stimulus and current response
signal could also be used to obtain heart impedance information. One example of
using a high frequency carrier signal to provide a test stimulus and obtain a thoracic

25   impedance response is discussed in Hartley et al. U.S. Patent No. 6,076,015 ("the
Hartley et al. patent") entitled "RATE ADAPTIVE CARDIAC RHYTHM
MANAGEMENT DEVICE USING TRANSTHORACIC IMPEDANCE," assigned
to Cardiac Pacemakers, Inc., the disclosure of which is incorporated herein by

8

reference in its entirety.

In one embodiment, the response signal sensed by signal processor **155** is a voltage that, for the given test current, represents a thoracic impedance (i.e., a resistive or reactive impedance associated with at least a portion of a thorax of a living organism). This thoracic impedance signal is influenced by the patient's

5 thoracic intravascular fluid tension, heart beat, and breathing (also referred to as "respiration" or "ventilation"). A "dc" or "baseline" or "low frequency" component of the thoracic impedance signal (e.g., less than a cutoff value that is approximately between 0.1 Hz and 0.5 Hz, inclusive, such as, for example, a cutoff value of approximately 0.1 Hz) provides information about the subject patient's thoracic

10 fluid tension, and is therefore influenced by intravascular fluid shifts to and away from the thorax. Higher frequency components of the thoracic impedance signal are influenced by the patient's breathing (e.g., approximately between 0.05 Hz and 2.0 Hz inclusive) and heartbeat (e.g., approximately between 0.5 Hz and 10 Hz inclusive).

15 As discussed above, a too-low intravascular fluid tension in the thorax ("thoracic hypotension") may result from changes in posture. This is sometimes referred to as orthostatic hypotension. For example, in a person who has been in a recumbent position for some time, approximately 1/3 of the blood volume is in the thorax. When that person then sits upright, approximately 1/3 of the blood that was

20 in the thorax migrates to the lower body. This increases thoracic impedance. Approximately 90% of this fluid shift takes place within 2 to 3 minutes after the person sits upright.

Aside from such changes in posture, however, thoracic hypotension may also manifest itself as disautonomic syncope or vasovagal syncope, or other condition in

25 which intravascular fluid shift from the thorax may or may not correspond directly to a change in the patient's posture. According to the present techniques, however, hypotension resulting from a fluid shift away from the thorax is indicated by an increase in the baseline thoracic impedance, regardless of whether the cause of the

9

hypotension is orthostatic. In response to the detection of hypotension, system **100** provides a therapy, such as by increasing the patient's heart rate by delivering pacing stimuli to the heart more rapidly. Upon detecting thoracic hypotension, signal processor **155** outputs an indicated rate signal at node/bus **160** to controller **165**. In one embodiment, based on the indicated rate signal at node **160**, controller **165**

5   adjusts the rate of delivery of cardiac rhythm management therapy, such as electrical pacing stimuli, to heart **115** by therapy circuit **170**. Such pacing stimuli includes, for example, providing bipolar pacing between tip electrode **120** and ring electrode **125**, providing unipolar pacing between can electrode **135** and either of tip electrode **120** or ring electrode **125**, or providing pacing stimuli using any other suitable electrode

10   configuration. By increasing pacing rate in this manner, system **100** effects a faster return of blood from the extremities to the thorax and head, thereby reducing or avoiding the symptoms of dizziness or fainting. By using thoracic impedance to directly measure thoracic intravascular fluid tension, rather than measuring a change of posture or other secondary variable, system **100** provides more reliable treatment

15   of thoracic hypotension and its associated symptoms. However, it is understood that in one embodiment, system **100** bases its treatment of hypotension based not only on the thoracic impedance-based measurement of intravascular fluid tension, but also one or more of these secondary variables (e.g., also using an accelerometer to detect a change in posture).

20   In another embodiment, the indicated pacing rate is not based solely on the intravascular thoracic fluid tension information obtained from the thoracic impedance signal. In one such embodiment, for example, the indicated pacing rate is also based on the patient's intrinsic heart rate, such as obtained by sensing intrinsic heart depolarizations using sense amplifier **175**. In other embodiments, the

25   intravascular fluid tension information is used in combination with at least one other indication of the patient's metabolic need for an increased heart rate. This other indication of metabolic need is obtained either from the same thoracic impedance sensor technique discussed above (but using other thoracic impedance information

10

such as, for example, breathing or heart rate) or from a completely different sensor. One example of such a different sensor is an accelerometer used to sense the patient's activity as a sensor-driven indicator of the need for a higher heart rate. An example of a "minute ventilation" technique of using the breathing information carried by the thoracic impedance signal as an indication of the patient's metabolic

5 need for a higher heart rate is discussed in Hartley et al. U.S. Patent No. 6,076,015 ("the Hartley et al. patent") entitled "RATE ADAPTIVE CARDIAC RHYTHM MANAGEMENT DEVICE USING TRANSTHORACIC IMPEDANCE," assigned to the assignee of the present invention, the disclosure of which is incorporated herein by reference in its entirety. The background portion of the Hartley et al.

10 patent also discusses a number of other sensors and techniques for providing an indication of metabolic need for adjusting the heart rate; it is understood that such techniques, or any other technique known in the art, could be blended or otherwise used in combination with the techniques discussed herein for increasing heart rate in response to an increase in the baseline transthoracic impedance corresponding to

15 intravascular fluid hypotension. The Hartley et al. patent also discusses in detail one technique for obtaining transthoracic impedance information using exciter 150, however, it is understood that the present invention is not limited to such technique, but could use any known technique for providing a test signal and sensing a resulting impedance.

20   Signal Processor

Figure 2 is a block diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of portions of signal processor 155. In this embodiment, signal processor 155 includes analog signal processing circuit 200 and digital signal processing circuit 205. Inputs of a preamplifier 210 (also referred to as

25 a preamp or a receiver) of analog signal processing circuit 200 are electrically coupled to each of indifferent electrode 145 and tip electrode 120 for receiving a signal in response to the above-discussed stimuli provided by exciter 150. Analog signal processing circuit 200 also includes demodulator 215, receiving the output of

11

preamplifier **210**, and providing a demodulated output signal to analog-to-digital (A/D) converter **225**. An output signal from A/D converter **225** is received at lowpass filter (or averager) **230** of digital signal processing circuit **205**. The Hartley et al. patent discusses the structure and operation of one embodiment of preamp **210** and demodulator **215**.

5   In one embodiment, digital signal processing circuit **205** is included within controller **165** such as, for example, as a sequence of instructions executed by a microprocessor. In another embodiment, digital signal processing circuit **205** includes separately implemented hardware portions dedicated to performing the digital signal processing tasks discussed below. Hypotension detection module **240**

10   receives an output signal from the averager or other lowpass filter **230**, and provides an indication of the hypotension at node **160** to controller **165**, which controls the rate at which pacing stimuli pulses are issued by therapy circuit **170**.

        Figure **3** is a schematic/block diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of portions of hypotension

15   detection module **240**. This embodiment provides a digital comparator **300** and a memory storage location, such as delay **305**, for storing a previous baseline thoracic impedance received from lowpass filter or averager **230**. In one embodiment, this delay is approximately between 3 and 120 seconds inclusive (e.g., 30 seconds). By comparing a difference between the present baseline thoracic impedance and its

20   previous value to a threshold value, comparator **300** provides an output signal that indicates the presence of thoracic hypotension to controller **165**. Comparator **300** includes embodiments both with and without hysteresis. In an alternative embodiment, comparator **300** is replaced by a difference circuit that provides, instead of a binary indication of thoracic hypotension, a multi-valued indication of

25   the magnitude of the thoracic hypotension.

        Figure **4** is a schematic/block diagram illustrating generally, by way of example, but not by way of limitation, another embodiment of portions of hypotension detection module **240**. This embodiment includes a digital comparator

12

300 that receives the baseline thoracic impedance from lowpass filter or averager **230** as well as an unfiltered (or lesser filtered) "instantaneous" thoracic impedance from A/D converter **225**. By comparing a difference between the present baseline impedance and the present "instantaneous"thoracic impedance to a threshold value, comparator **300** provides an output signal that indicates the presence of thoracic

5 hypotension to controller **165**. Comparator **300** includes embodiments both with and without hysteresis. In an alternative embodiment, comparator **300** is replaced by a difference circuit that provides, instead of a binary indication of thoracic hypotension, a multi-valued indication of the magnitude of the thoracic hypotension. It is understood that the embodiments of Figures **3** and **4** may be combined, for

10 example, to base the indication of thoracic hypotension on both the unfiltered and lowpass filtered thoracic impedance signals.

In one embodiment, hypotension detection module **240** indicates the detection of thoracic hypotension based on an increase of approximately between 2 and 20 ohms inclusive (e.g., 6 ohms) in the received lowpass filtered thoracic

15 impedance signal, which, in one embodiment, is averaged such as using a fixed or moving window average over a time period that is approximately between 5 seconds and 5 minutes inclusive (e.g., 1 minute). However, it is understood that lowpass filter **230** need not be an averager; other embodiments include a digital (or, if moved before A/D converter **225**, analog) filter having an effective cutoff frequency (i.e.,

20 effective 3 dB attenuation point of a single or multiple pole filter) that passes a signal associated with thoracic fluid shift and attenuates a higher frequency signal such as that associated with the patient's breathing or heart beat.

In another embodiment, hypotension detection module **240** also receives a thoracic impedance signal from A/D converter **225**, without being filtered or

25 averaged (or alternatively, averaged over a shorter time period) by lowpass filter or averager **230**. In this embodiment, hypotension detection module **240** uses this unfiltered thoracic impedance signal in combination with the averaged thoracic impedance signal, output by lowpass filter or averager **230**, to indicate the detection

13

of thoracic hypotension. In one example, where this "instantaneous" or "unfiltered" thoracic impedance exceeds the averaged thoracic impedance (also referred to as the "baseline," "low-frequency," or "dc" thoracic impedance) by a threshold amount that is approximately between 2 and 30 ohms inclusive, then an indication of thoracic hypotension is triggered. Hypotension detection module **240** provides an

5 indication of detected hypotension, at node **160**, to controller **165**; this indication may be, among other things, a binary indication of whether hypotension is present or, alternatively, a signal that includes information about the degree of hypotension present (e.g., based on the change in baseline thoracic impedance and/or difference between the instantaneous and average thoracic impedance).

10 In response to the indication of thoracic hypotension received from hypotension detection module **240**, controller **165** provides an appropriate therapy such as by adjusting the rate of delivery of pacing therapy to heart **115**. In one embodiment, detection of hypotension triggers pacing at a particular rate programmed by the physician (e.g., 90, 100, 110, 120, 130 beats per minute) for a

15 particular period of time (e.g., 30 seconds to 10 minutes), and then reverts back to the previous pacing rate before hypotension was detected, or to a different pacing rate if so indicated by one or more other sensors. For example, if the patient had a paced or intrinsic heart rate of 60 beats per minute when hypotension is detected, controller **165** then paces the patient at a hypotension treatment rate of 110 beats per

20 minute, for example, to counter the hypotension. After the desired duration of this treatment, such as 2 minutes, for example, controller **165** returns to the previous rate of 60 beats per minute. If, for example, a minute ventilation, accelerometer, or other sensor indicates a metabolic need for a different rate, however (e.g., 70 beats per minute indicated by an accelerometer tracking patient activity) then controller **165**

25 returns to that appropriately indicated rate (e.g., 70 beats per minute indicated by the accelerometer). In a further variation of this and other embodiments, the rate change to or from the hypotension treatment rate is not instantaneous, but incorporates a rate-smoothing algorithm such as is known in the art.

In another embodiment, controller **165** responds to a detection of hypotension by triggering an incremental increase (e.g., 10, 20, 30 . . . 50 beats per minute) in the pacing rate over the previous paced or intrinsic rate for a particular period of time (e.g., 30 seconds to 10 minutes), and then reverts back to that previous pacing rate or other suitable rate such if so determined by other direct or

5   indirect sensors of metabolic need. For example, if hypotension is detected when a patient has a paced or intrinsic heart rate of 65 beats per minute, and an incremental increase of 30 beats per minute has previously been programmed, then controller **165** increases the pacing rate to 95 beats per minute for the programmed duration of this treatment, such as 5 minutes, for example, after which time it reverts back to 65

10   beats per minute unless a metabolic need sensor indicates that reversion to another rate is more appropriate. In a further embodiment, the incremental increase is itself a function of the intrinsic or sensor-indicated heart rate, so that a higher intrinsic or sensor-indicated rate results in a smaller (or larger) incremental change in pacing rate when hypotension is detected. In yet a further embodiment, the incremental rate

15   increase is a function of the degree of detected hypotension. In such an example, a larger increase in baseline thoracic impedance is associated with a larger incremental rate increase for treating the hypotension.

In a further embodiment, hypotension detected based on thoracic impedance is one factor used in providing a blended indicated pacing rate; the indicated pacing

20   rate is also based on at least one other factor such as the patient's breathing (e.g., using a minute ventilation technique) or activity (e.g., using an accelerometer technique). Figure **5** is a block diagram illustrating generally, by way of example, not by way of limitation, one embodiment of a blending module **500** in controller **165** or elsewhere that provides an indicated pacing rate based on activity, breathing,

25   and/or a thoracic impedance-based measurement of hypotension, each scaled appropriately to provide a desired response.

In yet another embodiment, controller **165** responds to a detection of hypotension by triggering the application of high voltage pacing or other increased

15

electrical stimulation such as, for example, to increase the contractility of the heart. This therapy is carried out either in combination with or in lieu of a rate increase. In one example, a patient being paced using pulses of 2.0 Volts and 0.5 milliseconds is treated, upon detection of hypotension, by pacing pulses at a voltage level approximately between 5 Volts and 50 Volts inclusive, a current level

5   approximately between 5 milliamperes and 200 milliamperes inclusive, and/or a pulsewidth approximately between 10 milliseconds and 100 milliseconds inclusive for a suitable time period (e.g., 1 minute) before returning the therapy to previous energy levels.

        In still another embodiment, controller **165** responds to the detection of

10   hypotension by triggering the application of drug therapy from an implantable or external drug delivery system. Thus, the present system envisions a broad range of therapeutic responses to hypotension detected from thoracic impedance.

<div align="center">Other Electrode Configuration Examples</div>

        Figure **1** illustrated an electrode configuration for measuring transthoracic

15   impedance in which a test current was provided between a ring electrode **125** and a housing electrode **135**, a resulting voltage is measured across tip electrode **120** and header electrode **145**, and a transthoracic impedance is calculated based on the measured voltage and test current. However, other embodiments use different electrode configurations to determine transthoracic impedance, some examples of

20   which are discussed below.

        In a first embodiment of determining transthoracic impedance using the electrodes illustrated in Figure **1**, the test current is provided between the ring electrode **125** and one of housing electrode **135** or header electrode **145**, and a resulting voltage is measured across tip electrode 120 and the other of housing

25   electrode **135** or header electrode **145**.

        In a second embodiment, the test current is provided between tip electrode **120** and one of housing electrode **135** or header electrode **145**, and the resulting voltage is measured between ring electrode **125** and the other of housing electrode

<div align="center">16</div>

135 or header electrode **145**.

In a third embodiment, the test current is provided between: (a) one of ring electrode **125** or tip electrode **120**; and (b) one of housing electrode **135** or header electrode **145**. A resulting voltage is measured across: (a) the same one of ring electrode **125** or tip electrode **120**; and (b) and the other of housing electrode **135** or

5 header electrode **145**.

In a fourth embodiment, the test current is provided between: (a) one of housing electrode **135** or header electrode **145**; and (b) one of tip electrode **120** or ring electrode **125**. A resulting voltage is measured across: (a) the same one of housing electrode **135** or header electrode **145**; and (b) the other one of tip electrode

10 **120** or ring electrode **125**.

Figure **6** illustrates generally a cardiac rhythm management device **105** and a lead that includes a tip electrode **120**, a first coil or other defibrillation electrode **600** associated with a right ventricle **115A** of heart **115**, and a second coil or other defibrillation electrode **605** associated with a right atrium **115B** of heart **115**.

15 In a first embodiment of determining transthoracic impedance using the electrodes illustrated in Figure **6**, the test current is provided between the first defibrillation electrode **600** and one of housing electrode **135** or header electrode **145**, and a resulting voltage is measured across tip electrode **120** and the other of housing electrode **135** or header electrode **145**.

20 In a second embodiment, the test current is provided between tip electrode **120** and one of housing electrode **135** or header electrode **145**, and the resulting voltage is measured between first defibrillation electrode **600** and the other of housing electrode **135** or header electrode **145**.

In a third embodiment, the test current is provided between: (a) one of first

25 defibrillation electrode **600** or tip electrode **120**; and (b) one of housing electrode **135** or header electrode **145**. A resulting voltage is measured across: (a) the same one of first defibrillation electrode **600** or tip electrode **120**; and (b) and the other of housing electrode **135** or header electrode **145**.

17

In a fourth embodiment, the test current is provided between: (a) one of housing electrode **135** or header electrode **145**; and (b) one of tip electrode **120** or first defibrillation electrode **600**. A resulting voltage is measured across: (a) the same one of housing electrode **135** or header electrode **145**; and (b) the other one of tip electrode **120** or first defibrillation electrode **600**.

5   In a fifth embodiment, the test current is provided between second defibrillation electrode **605** and one of housing electrode **135** or header electrode **145**. A resulting voltage is measured across second defibrillation electrode **605** and the other of housing electrode **135** or header electrode **145**.

     Figure 7 illustrates generally a cardiac rhythm management device **105** and a

10   lead that includes a tip electrode **700** and ring electrode **705** associated with a right atrium **115B** of heart **115**.

     In a first embodiment of determining transthoracic impedance using the electrodes illustrated in Figure 7, the test current is provided between the ring electrode **705** and one of housing electrode **135** or header electrode **145**, and a

15   resulting voltage is measured across tip electrode **700** and the other of housing electrode **135** or header electrode **145**.

     In a second embodiment, the test current is provided between tip electrode **700** and one of housing electrode **135** or header electrode **145**, and the resulting voltage is measured between ring electrode **705** and the other of housing electrode

20   **135** or header electrode **145**.

     In a third embodiment, the test current is provided between: (a) one of ring electrode **705** or tip electrode **700**; and (b) one of housing electrode **135** or header electrode **145**. A resulting voltage is measured across: (a) the same one of ring electrode **705** or tip electrode **700**; and (b) and the other of housing electrode **135** or

25   header electrode **145**.

     In a fourth embodiment, the test current is provided between: (a) one of housing electrode **135** or header electrode **145**; and (b) one of tip electrode **700** or ring electrode **705**. A resulting voltage is measured across: (a) the same one of

housing electrode 135 or header electrode 145; and (b) the other one of tip electrode 700 or ring electrode 705.

Figure 8 illustrates generally a cardiac rhythm management device 105 and a lead that includes a tip electrode 800 and ring electrode 805 associated with a left ventricle 115C of heart 115 by being introduced into a coronary sinus and/or great
5   cardiac vein and/or one of its tributaries in the left ventricular free wall, or by being epicardially placed in proximity to left ventricle 115C.

In a first embodiment of determining transthoracic impedance using the electrodes illustrated in Figure 8, the test current is provided between the ring electrode 805 and one of housing electrode 135 or header electrode 145, and a
10   resulting voltage is measured across tip electrode 800 and the other of housing electrode 135 or header electrode 145.

In a second embodiment, the test current is provided between tip electrode 800 and one of housing electrode 135 or header electrode 145, and the resulting voltage is measured between ring electrode 805 and the other of housing electrode
15   135 or header electrode 145.

In a third embodiment, the test current is provided between: (a) one of ring electrode 805 or tip electrode 800; and (b) one of housing electrode 135 or header electrode 145. A resulting voltage is measured across: (a) the same one of ring electrode 805 or tip electrode 800; and (b) and the other of housing electrode 135 or
20   header electrode 145.

In a fourth embodiment, the test current is provided between: (a) one of housing electrode 135 or header electrode 145; and (b) one of tip electrode 800 or ring electrode 805. A resulting voltage is measured across: (a) the same one of housing electrode 135 or header electrode 145; and (b) the other one of tip electrode
25   800 or ring electrode 805.

Figures 1 and 6 - 8 illustrate, among other things, configurations in which one or more electrodes is located inside of, or in close proximity to, heart 115, and one or more electrodes is located at a distance away from heart 115, such as, for

example, on pectorally or abdominally implanted device **105**. This distance

provides an effective portion of the thorax for which the transthoracic impedance is

sampled. However, a lesser distance may also be used for sampling thoracic

impedance, in fact, thoracic impedance may be sampled using electrodes in more

close proximity, such as an embodiment in which all electrodes are associated with

5   heart **115**, as illustrated in the examples of Figures **9** and **10**.

Some of the embodiments discussed above (e.g., that of Figure 1) use four

electrodes for measuring impedance. In such a technique for measuring impedance,

both electrodes used for sensing the voltage are different than both of the electrodes

used for delivering the test current, so that the impedance of the leads coupling the

10   test current source to the test current electrodes does not affect the voltage

measurement. However, this is not a requirement. A three electrode arrangement

(in which only one of the voltage sensing electrodes is different from the test current

electrode pair) or even a two electrode arrangement (using the same electrodes for

both delivering the test current and measuring the test voltage) may be used,

15   although such arrangements may result in a larger steady-state (i.e., offset)

component of the measured impedance due to the measurement apparatus and

unrelated to the steady-state thoracic tissue impedance.

<u>Conclusion</u>

The above-discussed system provides, among other things, a cardiac rhythm

20   management system using thoracic impedance measurements to detect and treat

hypotension. It detects and treats hypotension that results either from a change in

posture or is independent of any change in posture. It is to be understood that the

above description is intended to be illustrative, and not restrictive. For example, the

above-discussed embodiments may be used in combination with each other. Many

25   other embodiments will be apparent to those of skill in the art upon reviewing the

above description. The scope of the invention should, therefore, be determined with

reference to the appended claims, along with the full scope of equivalents to which

such claims are entitled. In the appended claims, the terms "including" and "in

20

which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." The term "lowpass filter" is understood to include, among other things, any averager, and use of the term "averager/lowpass filter" is used simply to emphasize that an averager is included in the term "lowpass filter."